

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

In re: CEPHALON SECURITIES	:	
LITIGATION	:	CIVIL ACTION
	:	
	:	No. 96-0633
	:	

**MEMORANDUM-ORDER**

**GREEN, S.J.**

**October 22, 1998**

Presently before the court is Defendants' Motion for Protective Order under Federal Rule of Civil Procedure 26(c) and Plaintiffs' Response thereto. Defendants seek protection for five documents which have already been produced to Plaintiffs: (1) the Food and Drug Administration ("FDA") Briefing Document for the June 7, 1996 FDA Advisory Committee meeting; (2) a November 29, 1995 internal Cephalon memorandum from Michael Murphy to Frank Baldino; (3) a March 13, 1996 internal Cephalon memorandum from Steve Hardiman to distribution; (4) an August 20, 1996 internal Cephalon memorandum from Tom Dobbins to Frank Baldino; and (5) a November 20, 1995 letter from the New England Journal of Medicine to Dr. Eugene C. Lai. Plaintiffs argue that Defendants have not shown that the information contained within the documents in question is not known or available to the public and that any information in the documents beyond what is available to the public is a trade secret.

Federal Rule of Civil Procedure 26(c)(7) provides that the court may enter a protective order providing "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way." Fed. R. Civ. P. 26(c)(7).

**(1) The FDA Briefing Document**

Defendants seek to protect a document titled "FDA Briefing Document" which is addressed to the members of the Peripheral and Central Nervous System Drugs Advisory

Committee. Cephalon also was given a copy of the document. Plaintiffs argue that this document was disseminated to the members of the Advisory Committee who are mostly academicians and private practice clinicians, for use in connection with a public hearing, and nothing on the face of this document indicates that committee members were cautioned not to reveal its contents at the FDA public hearing. Much of the information in the document was disclosed to the public at the meeting.

Because much of the information contained in the FDA document has already been disclosed to the public and Defendants have failed to identify specifically what information in that document has not already been made public, this court is unable to assess what information, if any, contained in the document may be entitled to confidentiality. With regard to the FDA Briefing document, this court will deny Defendants' Motion for Protective Order without prejudice to file a new motion for protective order relating to the FDA briefing document and setting forth with particularity exactly what information in the FDA briefing document they seek to remain confidential and why said information is entitled to protection under Rule 26(c).

## **(2) The Murphy Memorandum**

Defendants seek to protect an internal Cephalon memorandum that discusses the biostatistical methods used to conduct the analyses of the data in study 1202. Defendants argue that this information is protectable because it discloses the methods and analyses used by Cephalon to interpret the study data, including the advantages and disadvantages of the different possible approaches. Upon review of the Murphy memorandum, this court concludes that the defendants have not shown how the discussion of the methods used by Cephalon to interpret the study data is information which constitutes a protectable trade secret.

### **(3) The Hardiman Memorandum**

Defendants seek to protect a memorandum written by Steve Hardiman, a Cephalon biostatistician, which memorializes a telephone conversation between himself and David Hoberman, the FDA biostatistician that was assigned to the Myotrophin case. Defendants argue that this conversation reveals the internal decision-making and thought processes of both Cephalon and the FDA. Plaintiffs respond by arguing that this document discusses the FDA position on various matters. As the subject-matter of the Hardiman Memorandum does appear to be in large part the opinions of Mr. Hoberman, the FDA biostatistician, not of Mr. Hardiman, the Cephalon biostatistician, this court concludes that Defendants have failed to demonstrate that the information in this document constitutes a protectable trade secret. Defendants have also failed to establish how anything said by Mr. Hardiman in that conversation qualifies as a trade secret.

### **(4) The Dobbins Memorandum**

The Dobbins Memorandum is an internal Cephalon memorandum distributed to Dr. Baldino and two other senior officers of the company. The document appears to be a summary of a meeting with the FDA, and the subject of the memo is noted as “Summary of key points made by the agency.” Defendants argue that this document should be protected because it summarizes the FDA’s thinking about Myotrophin at the time. Upon review of the document, Defendants have failed to demonstrate how the information in this document can constitute a trade secret entitled to protection under Rule 26(c)(7).

### **(5) Letter from the New England Journal of Medicine (NEJM) to Dr. Lai**

This letter communicated the NEJM’s decision not to publish Dr. Lai’s article concerning the 1200 study and included comments of three reviewers. Defendants argue that the letter and

comments of reviewers reveal information about the methods and analyses of Cephalon. As this document was written by NJEM, this court concludes that Defendants have failed to establish how this information could possibly constitute a trade secret.

An appropriate Order follows.

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**ORDER**

AND NOW, this 22nd day of October, 1998, upon consideration of Defendants' Motion for Protective Order under Federal Rule of Civil Procedure 26© and Plaintiffs' Response thereto, IT IS HEREBY ORDERED that:

1. Defendants' Motion is DENIED with respect to the Murphy Memorandum dated November 29, 1995; the Hardiman Memorandum dated March 13, 1996; the Dobbins Memorandum dated August 20, 1996; and the NJEM letter dated November 20, 1995.

2. With respect to the FDA Briefing Document, Defendants' Motion is DENIED without prejudice to file a new motion within ten (10) days of the date of this Order setting forth with particularity exactly what information in the FDA briefing document they seek to remain confidential and why said information is entitled to protection under Rule 26(c).

3. In accordance with the terms of the Confidentiality Stipulation and Order, the documents that are the subject of this Order shall be treated as "confidential" until ten (10) business days after the date of this Order. After such date, the documents will no longer be designated as confidential and will not be under any protection from the court. In the event Defendants file a new motion regarding the FDA briefing document within ten (10) days of the date of this Order, the FDA briefing document will continue to be treated as "confidential" until

ten (10) days after this court enters an order on the new motion.

BY THE COURT:

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CLIFFORD SCOTT GREEN, S.J.